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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/761,032

01/20/2004

Robert Falotico

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05/15/2007

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EXAMINER

KENNEDY, SHARON E

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

05/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/761,032	Applicant(s) FALOTICO ET AL.	
	Examiner Sharon E. Kennedy	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/04/2005; 09/28/2005</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "incompatible" is vague and indefinite because it does not state with specificity the nature of the polymeric layers.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8, 9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sirhan et al., US 6,471,908. See especially figures 7 and 8, showing the multiple layers. Figure 7 shows stent/scaffold 10 coated with rate limiting barrier 28 including mycophenolic acid. Note matrix 20 layered over rate limiting barrier 28, and additional layer 30 which may comprise a third layer. Either layer 30 or 20 anticipate the claimed topcoat controlling the elution rate. See also column 5, lines 1-11, disclosing that other drugs may be disposed in a different layer or within the same layer, the drug being rapamycin (column 5, line 14), for example. Regarding claim 6, note column 5, lines

25+, disclosing that the rate limiting barrier may be adjacent to the structure (note also Figure 8) and which may be PTFE. Regarding claim 8, applicant states in the specification that "incompatible" means that one coating is hydrophobic and the other is hydrophilic. The examiner is ascribing this limitation to the meaning of "incompatible" as claimed. Sirhan shows a PTFE rate limiting barrier in combination with a matrix coating 20 which may be a polylactic acid, for example. Regarding claim 9, Sirhan discloses various formulations for the coatings, including stating that the rate limiting barrier 28 may contain additional therapeutics. See column 5, lines 35-56.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan '980 in view of Pinchuk et al., US 6,545,097. Sirhan does not disclose the acrylic coating, however, it is not reasonable to expect Sirhan to list every possible type of polymeric coating which may be used in the invention. Sirhan makes this clear in the patent by stating that polymers useful for the matrix "include polyanhydrides," polylactic acids, etc. See column 4, line 49. Accordingly, this list is not an exhaustive naming of all possible polymers, merely a suggestion of suitable polymers of a similar nature, with a clear understanding that others having similar properties would also be suitable.

Applicant claims that the polymer may be an acrylic. Acrylic polymers are similar in design and characteristics as those described by Sirhan. The secondary reference, Pinchuk discloses a stent which may be coated with various polymers as set forth in column 2, lines 40-55. Note that the polyacrylic acids are disclosed in the list with polylactic acids, polyglycolic acids, etc. This patent exemplifies that stent coatings for sustained release which are biodegradable encompass a wide variety, and that the polymers claimed by applicant and shown by Sirhan are similar and interchangeable. Further, applicant's specification has been carefully examined for any particular significance attached to the polyacrylic coating, which may be used to show an unexpected result, however, none is found. Accordingly, the claim is rejected.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The patent to Morris et al., US 5,646,160, is cited to exemplify

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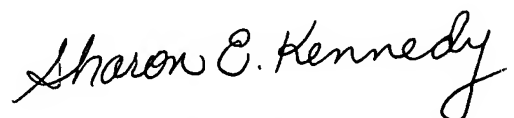
that the concept of applying the combination of rapamycin and mycophenolic acid to stents is well known.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sharon E. Kennedy
Primary Examiner
Art Unit 1615